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Attorney Docket No.: 15280-403100US Client Reference No.: E-194-99/1

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Peter L. Collins et al.

Application No.: 09/611,829

Filed: July 7, 2000

For: PRODUCTION OF ATTENUATED RESPIRATORY SYNCYTIAL VIRUS

VACCINES INVOLVING MODIFICATION OF M2 ORF2

Examiner:

Unassigned

Art Unit:

1645

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §1.97 and

§1.98

Assistant Commissioner for Patents Washington, D.C. 20231

Sir:

The references cited on attached form PTO-1449 are being called to the attention of the Examiner. Copies of the references are enclosed. It is respectfully requested that the cited references be expressly considered during the prosecution of this application, and the references be made of record therein and appear among the "references cited" on any patent to issue therefrom.

Applicants believe that their invention as claimed is patentable over the above references taken alone or in any combination. As provided for by 37 CFR 1.97(g) and (h), no inference should be made that the information and references cited are prior art merely because they are in this statement and no representation is being made that a search has been conducted

PETER COLLIN .t al. Application No.: 09/611,829

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or that this statement encompasses all the possible relevant information. No inference should be drawn as to the pertinence of the references based on the order in which they are presented.

It is further requested that the disclosure and claims presently or subsequently presented in the following, copending U.S. Patent Applications, as well as any related applications now or subsequently claiming priority to one or more of the following U.S. Patent Applications, be expressly considered and made of record in the instant case as potentially disclosing or claiming subject matter material to examination of the present application.

- U.S. Patent Application No. 08/453,304, filed on 05/30/95, by Murphy et al.;
- U.S. Patent Application No. 08/720,132, filed on 09/27/96, by Collins;
- U.S. Patent Application No. 09/291,894, filed on 04/13/99, by Collins et al.;
- U.S. Patent Application No. 09/350,821, filed on 07/09/99, by Durbin et al.;
- U.S. Patent Application No. 09/444,067, filed on 11/19/99, by Murphy et al.;
- U.S. Patent Application No. 09/444,221, filed on 11/19/99, by Murphy et al.;
- U.S. Patent Application No. 09/602,212, filed on 06/23/00, by Buchholz et al.;
- U.S. Patent Application No. 09/611,829, filed on 07/07/00, by Collins et al.;
- U.S. Patent Application No. 09/614,285, filed on 07/12/00, by Collins;
- U.S. Provisional Patent Application No. 60/213,708, filed on 06/23/00, by Krempl et al.

Applicant believes that <u>no fee is required</u> for submission of this statement, since it is being submitted prior to the first Office Action. However, if a fee is required, the Commissioner is authorized to deduct such fee from the undersigned's Deposit Account No. 20-1430.

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Please deduct any additional fees from, or credit any overpayment to, the abovenoted Deposit Account.

Respectfully submitted,

Dated: <u>4/6</u>

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InitialAA 5,	S AND PUBLI FORMATION se several sheets	DISCLOSURE if necessary)	Attorney Docket No.: 1528 Applicant: Peter L. Collins Filing Date: July 7, 2000		Application No.	: 09/611,829	
APPLICANT'S INF STATEMENT (Use Reference Designate Examiner Initial AA 5,	FORMATION e several sheets ion	DISCLOSURE if necessary)		et al.	Τ		
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Initial AA 5,	ocument No.		U.S. PATENT DOCUMENT	rs		Page 1	
		Date	Name	Class	Sub-class	Filing Date (If	
_	716,821	02/20/98	Wertz et al.	435	235.1	Appropriate)	
AB 5,	789,229	08/04/98	Wertz et al.	435	235.1		
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AY Bai	Bailly et al., "A Recombinant Human Parainfluenza Virus Type 3 (PIV3) in Which the Nucleocapsid N Protein Has Been Replaced by That of Bovine PIV3 Is Attenuated in Primates," J. Virol. 74:3188-3195, 2000						
AZ Bar	Baron et al., "Rescue of Rinderpest Virus from Cloned cDNA," J. Virol. 71:1265-1271, 1997						
	Bermingham et al., "The M2-2 Protein of Human Respiratory Syncytial Virus is a Regulatory Factor Involved in the Balance Between RNA Replication and Transcription," Proc. Natl. Acad. Sci. USA 96:11259-11264, 1999						
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LIST OF PATENTS AND PUBLICATIONS FOR		Applicant: Peter L. Collins et al.	
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BC	Buchholz et al., "Chimeric Bovine Respriatory Syncytial Virus (HRS' J. Virol. 74:1187-1199, 2000	Respiratory Syncytial Virus with Glycoprotein V): Effects on Host Range and Evaluation as a	n Gene Substitutions from human a Live-Attenuated HRSV Vaccine,"
BD	Buchholz et al., "Generation of Bovine Respiratory Syncytial Virus (BRSV) from cDNA: BRSV NS2 Is Not Essential for Virus Replication in Tissue Culture, and the Human RSV Leader Region Acts as a Functional BRSV Genome Promoter," J. Virol. 73:251-259, 1999		
BE	Bukreyev, et al., "Recovery of Infectious Respiratory Syncytial Virus Expressing an Additional, Foreign Gene," <u>J. Virol.</u> 70:6634-41, 1996		
BF	Bukreyev, et al., "Recombinant Respiratory Syncytial virus from which the Entire SH Gene has been Deleted Grows Efficiently in Cell Culture and Exhibits Site-Specific Attenuation in the Respiratory Tract of the Mouse," <u>J. Virol.</u> 71:8973-8982, 1997		
BG	Bukreyev, et al., "Interferon γ Expressed by a Recombinant Respiratory Syncytial Virus Attenuates Virus Replication in Mice Without Compromising Immunogenicity," Proc. Nat. Acad. Sci. USA 96:2367-2372, 1999		
ВН	Collins and Wertz, "The Envelope-Associated 22K Protein of Human Respiratory Syncytial Virus: Nucleotide Sequence of the mRNA and a Related Polytranscript," J. Virol. 54:65-71, 1985		
BI	Collins et al., "The Two Open Reading Frames of the 22K mRNA of Human Respiratory Syncytial Virus: Sequence Comparison of Antigenic Subgroups A and B and Expression iin vitro," J. Gen. Virol 71:3015-3020, 1990		
BJ	Collins et al., "Rescue of Synthetic Analogs of Respiratory Syncytial Virus Genomic RNA and Effect of Truncations and Mutations on the Expression of a Foreign Reporter Gene," <u>Proc. Natl. Acad. Sci. USA</u> , 88:9663-9667, 1991		
BK	Collins, et al., "Rescue of a 7502-Nucleotide (49.3% of Full-Length) Synthetic Analog of Respiratory Syncytial Virus Genomic RNA," <u>Virology</u> 195:252-256, 1993		
BL -	Collins, et al., "Production of Infectious Human Respiratory Syncytial Virus from Cloned cDNA Confirms an Essential Role of the Transcription Elongation Factor from the 5' Proximal Open Reading Frame of the M2 mRNA in Gene Expression and Provides a Capability for Vaccine Development," Proc Nat. Acad. Sci. USA 92:11563-11567, 1995		
BM	Collins et al., "Transcription Elongation Factor of Respiratory Syncytial virus, a Nonsegmented Negative-Strand RNA Virus," Proc. Natl. Acad. Sci. USA 93:81-85, 1996		
BN	Collins et al., "Support Plasmids and Support Proteins Required for Recovery of Recombinant Respiratory Syncytial Virus," Virology 259:251-255, 1999		
BO	Conzelmann et al., "Rescue of Synthetic Genomic RNA Analogs of Rabies Virus by Plasmid-Encoded Proteins," <u>J. Virol.</u> 68:713-719, 1994		
BP	Conzelmann, "Genetic Manipulation of Non-Segmented Negative-strand RNA Viruses," J. Gen. Virol. 77:381-389, 1996		
BQ	Corvaia et al.,"Challenge of BALB/c Mice with Respiratory Syncytial Virus does not Enhance the Th2 Pathway Induced after Immunization with a Recombinant G Fusion Protein, BBG2NA, in Aluminum Hydroxide," <u>J. Infec. Dis.</u> 176:560-569, 1997		
BR	Crowe, et al., "A Further Attenuated Derivative of a Cold-Passaged Temperature-Sensitive Mutant of Human Respiratory Syncytial Virus Retains Immunogenicity and Protective Efficacy Against Wild-Type Challenge in Seronegative Chimpanzees," <u>Vaccine</u> 12:783-790, 1994		
BS	Crowe, et al., "Acquisition of the ts Phenotype by a Chemically Mutagenized Cold-Passaged Human Respiratory Syncytial Virus Vaccine Candidate Results from the Acquisition of a Single Mutation in the Polymerase (L) Gene," Virus Genes 13:269-273, 1996		
BT ⁻	Delenda, et al., "Normal Cellular Replication of Sendai Virus Without the trans-Frame, Nonstructural V Protein," <u>Virology</u> 228:55-62, 1997		
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LIST OF PATENTS AND PUBLICATIONS FOR		Applicant: Peter L. Collins et al.		
	INFORMATION DISCLOSURE (Use several sheets if necessary)	Filing Date: July 7, 2000	Group: 1645	
BU	Ding et al., "Expression and Glycosylation of the Respiratory Syncytial Virus G Protein in Saccharomyces cerevisiae," Virology 159:450-453, 1987			
BV	Elango et al., "Resistance to Human Respiratory Syncytial Virus (RSV) Infection Induced by Immunization of Cotton Rats with a Recombinant Vaccinia Virus Expressing the RSV G Glycoprotein," Proc. Natl. Acad. Sci. USA 83:1906-1910, 1986			
BW	Falsey and Walsh, "Safety and Immunogenicity of a Respiratory Syncytial Virus Subunit Vaccine (PFP-2) in the Institutionalized Elderly," <u>Vaccine</u> 15:1130-1132, 1997			
BX	Fearns and Collins, "Role of the M2-1 Transcription Antitermination Protein of Respiratory Syncytial Virus in Sequential Transcription," J. Virol. 73:5852-5864, 1999			
BY	Firestone, et al., "Nucleotide Sequence Analysis of the Respiratory Syncytial Virus Subgroup A Cold-Passaged (cp) Temperature Sensitive (ts) cpts-248/404 Live Attenuated Live Virus Candidate," Virology 225: 419-422, 1996			
BZ	Graham et al., "Priming Immunization Determines T Helper Cytokine mRNA Expression Patterns in Lungs of Mice Challenged with Respiratory Syncytial Virus," J. Immun. 151:2032-2040, 1993			
CA	Hardy et al., "The Product of the Respiratory Syncytial Virus M2 Gene ORF1 Enhances Readthrough of Intergenic Junctions During Viral Transcription," J. Virol. 72:520-526, 1998			
СВ	He et al., "Recovery of Infectious SV5 from Cloned DNA and Expression of a Foreign Gene," Virology 237:249-260, 1997			
cc	He et al., "The Paramyxovirus SV5 Small Hydrophobic (SH) Protein is not Essential for Virus Growth in Tissue Culture Cells," Virology 250:30-40, 1998			
CD	Jin et al., "Respiratory Syncytial Virus that Lacks Open Reading Frame 2 of the M2 Gene (M2-2) has Altered Growth Characteristics and is Attenuated in Rodents," J. Virol, 74:74-82, 2000			
CE	Kato et al., "The Paramyxovirus, Sendai Virus, V Protein Encodes a Luxury Function Required for Viral Pathogenesis," EMBO. J. 16:578-587, 1997			
CF	Kuo et al., "Effect of Mutations in the Gene-Start and Gene-End Sequence Motifs on Transcription of Monocistronic and Dicistronic Minigenomes of Respiratory Syncytial Virus," J. Virol, 70:6892-6901, 1996			
CG	Kurotani et al., "Sendai Virus C Proteins are Categorically Nonessential Gene Products but Silencing Their Expression Severely Impairs Viral Replication and Pathogenesis," Genes to Cells. 3:111-124, 1998.			
СН	Latorre et al., "The Various Sendai Virus C Proteins Are Not Functionally Equivalent and Exert both Positive and Negative Effects on Viral FNA Accumulation During the Course of Infection," J. Virol. 72:5984-5993, 1998			
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CJ	Levely et al., "Synthetic Immunogens Constructed from T-Cell and B-Cell Stimulating Peptides (T:B Chimeras): Preferential Stimulation of Unique T- and B-Cell Specificities is Influenced by Immunogen Configuration," Cell. Immun., 125:65-78, 1990			
CK	Ling et al., "Sequence Analysis of the 22K, SH and G Genes of Turkey Rhinotracheitis virus and their Intergenic Regions Reveals a Gene Order Different from that of Other Pneumoviruses," J. Gen. Virol. 73:1709-1715, 1992			
CL	Mallipeddi, et al., "Sequence Comparison Between the Phosphoprotein mRNAs of Human and Bovine Respriatory Syncytial Viruses identifies a Divergent Domain in the Predicted Protein," J. Gen. Virol. 73:2441-2444, 1992			
СМ	Mallipeddi, et al., "Sequence Variability of the Glycoprotein Gene of Bovine Respiratory Syncytial Virus," <u>J. Gen. Virol.</u> 74:2001-2004, 1993			
CN	Martin-Gallardo et al., "Expression of the G Glycoprotein Gene of Human Respiratory Syncytial Virus in Salmonella typhimurium," J. Gen. Virol. 74:453-458, 1993			
co	Murby et al., "Hydrophobicity Engineering to Increase Solubility and Stability of a Recombinant Protein from Respiratory Syncytial Virus," Eur. J. Biochem. 230:38-44, 1995			
CP	Murphy et al., "Current Approaches to the Development of Vaccines Effective Against Parainfluenza and Respiratory Syncytial Viruses," Virus Res 11:1-15, 1988			
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE		Applicant: Peter L. Collins et al.		
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co	Murphy et al., "Enhanced Pulmonary Histopathology is Observed in Cotton Rats Immunized with Formalin-inactivated Respiratory Syncytial Virus (RSV) or Purified F Glycoprotein and Challenged with RSV 3-6 Months after Immunization," <u>Vaccine</u> 8:497-502, 1990			
CR	Oien et al., "Induction of Local and Systemic Immunity Against Human Respiratory Syncytial Virus Using a Chimeric FG Glycoprotein and Cholera Toxin B Subunit," <u>Vaccine</u> 12:731-735, 1994			
CS	Olmsted et al., "Expression of the F Glycoprotein of Respiratory Syncytial Virus by a Recombinant Vaccinia Virus: Comparison of the Individual Contribution of the F and G Glycoproteins to Host Immunity," <u>Proc. Natl. Acad. Sci. USA</u> 83:1906-1910, 1986			
CT	Palese et al., "Negative-Strand RNA Viruses: Genetic Engineering and Applications," Proc. Natl. Acad. Sci. USA 93:11354-11358, 1996			
cu	Pastey et al., "Nucleotide Sequence Analysis of the Non-Structural NS1(1C) and NS2 (1B) Protein Genes of Bovine Respiratory Syncytial Virus," J. of Gen. Virol. 76:193-197, 1995			
CV	Pastey et al., "Structure and Sequence Comparison of Bovine Respiratory Syncytial Virus Fusion Protein," Virus. Res. 29:195-202, 1993			
CW	Peeples et al., "Respiratory Syncytial Virus Polypeptides: Their Location in the Virion," Virology 95:137-145, 1979			
CX	Plotnicky-Gilquin et al., "Absence of Lung Immunopathology Following Respiratory Syncytial Virus (RSV) Challenge in Mice Immunized with a Recombinant RSV G Protein Fragment," Virology 258:128-140, 1999			
CY	Power et al., "Induction of Protective Immunity in Rodents by Vaccination with a Prokaryotically Expressed Recombinant Fusion Protein Containing a Respiratory Syncytial Virus G Protein Fragment," Virology 230:155-166,1997			
CZ	Radecke et al., "The Nonstructural C Protein is not Essential for Multiplication of Edmonston B Strain Measles Virus in Cultured Cells," Virology 217:418-21, 1996			
DA	Randhawa et al., "Nucleotide Sequences of the Genes Encoding the Putative Attachment Glycoprotein (G) of Mouse and Tissue Culture-Passaged Strains of Pneumonia Virus of Mice," Virology 207:240-245, 1995			
DB	Roberts et al., "Recovery of Negative-Strand RNA Viruses from Plasmid DNAs: A Positive Approach Revitalizes a Negative Field," Virology 247:1-6, 1998			
DC	Sakai et al., "Accommodation Of Foreign Genes Into The Sendai Virus Genome: Sizes Of Inserted Genes And Viral Replication," FEBS Letters 456:221-226, 1999			
DD	Schneider et al., "Recombinant Measles Viruses defective for RNA Editing and V Protein Synthesis Are Viable in Cultured Cells," Virology 227:314-322, 1997			
DE	Schnell et al., "Infectious Rabies Viruses from Cloned cDNA," EMBO J. 13:4195-4203, 1994			
DF	Siegrist et al., "Protective Efficacy Against Respiratory Syncytial Virus Following Murine Neonatal Immunization with BBG2Na Vaccine: Influence of Adjuvants and Maternal Antibodies," J. Infect. Dis. 179:1326-1333, 1999			
DG	Tebbey et al., "A Novel and Effective Intranasal Immunization Strategy for Respiratory Syncytial Virus," Viral Immunol. 12:41-45, 1999			
DH	Tebbey et al., "Atypical Pulmonary Eosinophilia is Mediated by a Specific Amino Acid Sequence of the Attachment (G) Protein of Respiratory Syncytial Virus," J. Exp. Med. 188:1967-1972, 1998			
DI	Teng et al., "Identification of the Respiratory Syncytial Virus Proteins Required for Formation and Passage of Helper-Dependent Infectious Particles," J. Virol. 72:5707-5716, 1998			
D1	Teng et al., "Altered Growth Characteristics of Recombinant Respiratory Syncytial Viruses Which do not Produce NS2 Protein," J. Virol. 73:466-473, 1999			
DK	Tristram et al., "Second-year Surveillance of Recipients of a Respiratory Syncytial Virus (RSV) F Protein Subunit Vaccine, PFP-1: Evaluation of Antibody Persistence and Possible Disease Enhancement," <u>Vaccine</u> 12:551-556, 1994			
DL	Trudel et al., "Protection of BALB/c Mice from Respiratory Syncytial Virus Infection by Immunization with a Synthetic Peptide Derived from the G Glycoprotein," Virology 185:749-757, 1991			
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LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (Use several sheets if necessary)		Applicant: Peter L. Collins et al.	
		Filing Date: July 7, 2000	Group: 1645
DM	Walsh et al., "Purification and Characterization of GP90, One of the Envelope Glycoproteins of Respiratory Syncytial Virus." J. Gen. Virol. 65:761-767, 1984		
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DO	Wathen et al., "Characterization of a Novel Human Respiratory Syncytial Virus Chimeric FG Glycoprotein Expressed Using a Baculovirus Vector," J. Gen Virol. 70:2625-2635, 1989		
DP	Wathen et al., "Immunization of Cotton Rats with the Human Respiratory Syncytial Virus F Glycoprotein Produced Using a Baculovirus Vector," J. Infect. Dis. 159:255-264, 1989		
DQ	Welliver and Tristram et al., "Respiratory Syncytial Virus-Specific Cell-Mediated Immune Responses after Vaccination with a Purified Fusion Protein Subunit Vaccine," J. Infect. Dis. 170:425-428, 1994		
DR	Wells et al., "Purification of a Recombinant Human Respiratory Syncytial Virus Chimeric Glycoprotein Using Reversed-Phase Chromatography and Protein Refolding in Guanidine Hydrochloride," <u>Protein Expr. Purif.</u> 5:391-340, 1994		
DS	Whelan et al., "Efficient Recovery Of Infectious Vesicular Stomatitis Virus Entirely From cDNA Clones," Proc. Natl. Acad. Sci. USA 92:8388-8392, 1995.		
DT	Whitehead et al., "A Single Nucleotide Substitution in the Transcription Start Signal of the M2 Gene of Respiratory Syncytial Virus Vaccine Candidate <i>cpts</i> 248/404 is the Major Determinant of the Temperature-Sensitive and Attenuation Phenotypes," <u>Virology</u> 247:232-239, 1998a		
DU	Whitehead et al., "Recombinant Respiratory Syncytial Virus (RSV) Bearing a Set of Mutations from cold-Passaged RSV is Attenuated in Chimpanzees," J. Virol. 72:4467-4471, 1998b		
DV	Whitehead et al., "Recombinant Respiratory Syncytial Virus Bearing a Deletion of Either the NS2 or SH Gene is Attenuated in Chimpanzees," J. Virol. 73:3438-3442, 1999		
DW	Zamora et al., "Gene Junction Sequences of Bovine Respiratory Synctytial Virus," Virus Res. 24:115-121, 1992		
DX	Zamora et al., "Sequence Analysis of M2 mRNA of Bovine Respiratory Syncytial Virus Obtained from an F-M2 dicistronic mRNA Suggests Structural Homology with that of Human Respiratory Syncytial Virus," J. Gen. Virol. 73:737-741, 1992		
EXAMINER		DATE CONSIDERED	

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.